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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,737	06/23/2003	Dieter Hochrainer	1/1223-1-C1	9030
28501	7590	12/12/2005	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			NGUYEN, DINH Q	
			ART UNIT	PAPER NUMBER
			3752	
DATE MAILED: 12/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,737

Applicant(s)

HOCHRAINER ET AL.

Examiner

Dinh Q. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a rotary bearing" in claim 1 and "indivisibly attached" in claim 3 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The abstract of the disclosure is objected to because it contains the phrase "the present invention relates to" should be deleted. Correction is required. See MPEP § 608.01(b).
4. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).
5. The use of the trademark RESPIMAT® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. The disclosure is objected to because of the following informalities: in page 2, line 5, the word "realizes" is misspelled. In page 3, line 12 and page 6, line 32, the word "round" should be replaced with --around--.

Appropriate correction is required.

Claim Objections

7. Claims 2-7 are objected to because of the following informalities: the word "characterized" is misspelled in each of the claims. Appropriate correction is required.

8. In claim 1, line 14, the limitation "a rotary bearing" is not clearly recited in the specification and drawing.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2, 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, recites the limitation "a locking mechanism" (line 12), "a spring housing with a spring" (line 13) appears to be double inclusions of the previously recited limitations: "a locking mechanism" (line 4), "a spring housing" (line 5), "a spring" (line 6).

Claim 2 recites the limitation "the outer contour" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the average particle size" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the spray mist" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 7 recites the limitation "the side wall" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. For the purpose of this Office action, the claims will be examined as best understood by the examiner.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 3, 4, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaeger et al. (U.S. Patent Number 5,964,416).

The statement of intended use carries no patentable weight.

Jaeger et al discloses an atomizer that does not require the use of a propellant comprising: an upper housing part 51, a locking mechanism 62, a spring housing 67, a spring 68, a pump housing 52 which is secured in the upper housing part and which comprises at one end a nozzle body 65, a hollow plunger 57 with valve body 58, a

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power takeoff flange 56 in which the hollow plunger is secured, a lower housing part 70, a storage vessel 71 for the liquid to be administered, and an adapter 66 in the form of a cavity surrounded by a wall with two openings, the adapter 66 is capable of surround the visible part of the eye.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable to Jaeger et al. (PCT publication WO 97/12687) in view of Cornish (U.S. Patent Number 5,578,021).

In regard to claims 1-2 and 4, Jaeger et al. disclose an atomizer with an upper housing part (51), a locking mechanism (61), and a spring housing (67) with a spring (68) contained therein, and which is rotatably mounted on the upper housing part by means of a rotary bearing. Jaeger et al. further disclose a pump housing (52) which is secured to the upper housing part, and which comprises at one end a nozzle body (54), with a nozzle. Jaeger et al. disclose a hollow plunger (57) with a valve body (58), a power takeoff flange (56) in which the hollow plunger is secured, and which is located in the upper housing part. Additionally, Jaeger et al. disclose a lower housing part (70) that is fitted onto the spring housing in an axial direction, and a storage vessel (71) to hold

the liquid to be administered. While Jaeger et al. disclose a projection extending upward and around the nozzle, they do not specifically disclose an adapter that surrounds the nozzle, and is contoured to fit the eye

Cornish discloses an eye medicament dispensing device, with an adapter (40) having two openings, that "maintains the upper and lower eye lids in a position to allow medicament to be delivered" (col. 2, lines 31-32). One opening (54) of the adapter surrounds the nozzle, and is fitted on a projection (26) close to the nozzle, so that spray emerging from the device is conveyed exclusively into the cavity created by the adaptor. The second opening (46) has an outer contour to surround the eye. As seen in Figures 1 and 2, the second opening of the adaptor is oval in plan view, and in the form of a concave curved line in cross section.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the atomizer as disclosed by Jaeger et al. with the adaptor disclosed by Cornish being attached to the atomizer, to maintain the position of the eye lids, while dispensing a medicament.

In regard to claim 3, Cornish discloses an "integrally attached" adaptor, but does not disclose that it is indivisibly formed with the body of the device.

It is an obvious substitution to replace the detachable adaptor disclosed by Cornish with an indivisibly attached adaptor to prevent loss of the device.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the atomizer as disclosed by Jaeger et al. with an adaptor as taught by Cornish, while replacing the detachable adaptor with one indivisibly formed, to

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prevent loss of the adaptor, and to maintain the position of the eye lids, while dispensing a medicament.

In regard to claim 7, Cornish does not disclose the placement of holes in the adaptor of the device.

While Cornish does not disclose such a feature, it is well known in the art to provide holes near a nozzle, to reduce pressure and allow the passage of excess medicament. For example, Jaeger et al. disclose the placement of holes (indicated on Figs. 6a-6b), proximate the nozzle of the atomizer to allow excess medicament to escape.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the atomizer as disclosed by Jaeger et al. with an adaptor as taught by Cornish, having holes in the sidewall of the device, proximate the nozzle, to allow excess medicament to escape.

16. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger et al. (U.S. Patent Number 5,964,416) in view of Weston et al. (U.S. Patent Number 5,497,944).

Jaeger et al. teaches all the limitations of the claims except for the average size or speed of the atomized particles. Weston et al. disclose an atomizing device, and state that medicament particles preferably have a size of less than 12 microns (col. 1, lines 17-19), and a speed of 30 meters per second (col. 16, lines 18-20), to achieve the proper dispersion of the medicament (lines 13-15). It would have been obvious to one skilled in the art to provide the atomizer as described by Jaeger et al. with the

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characteristics of the atomizer disclosed by Weston et al. to achieve the proper dispersion of the medicament.

17. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaeger et al. in view of Cornish, as applied to claims 1-4 and 7 above, and further in view of Weston et al. (U.S. Patent Number 5,497,944).

Jaeger et al. in view of Cornish disclose the previously described atomizer and adaptor. Jaeger et al., while cognizant of particle size and velocity, does not state the average size or speed of the atomized particles.

Weston et al. disclose an atomizing device, and state that medicament particles preferably have a size of less than 12 microns (col. 1, lines 17-19), and a speed of 30 meters per second (col. 16, lines 18-20), to achieve the proper dispersion of the medicament (lines 13-15).

It would have been obvious to one skilled in the art to provide the atomizer as described by Jaeger et al. with the characteristics of the atomizer disclosed by Weston et al. to achieve the proper dispersion of the medicament.

Conclusion

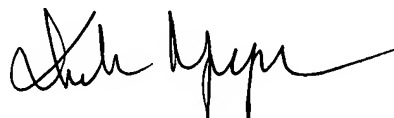
18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to show the art with respect to an atomizer: Smith et al., and Kirkham.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dinh Q. Nguyen whose telephone number is 571-272-4907. The examiner can normally be reached on Monday-Thursday 6:00-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Scherbel can be reached on 571-272-4919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dinh Q Nguyen
Primary Examiner
Art Unit 3752

dqn